

## § 868.5860

and reinfuse the blood lost by a patient due to surgery or trauma.

(b) *Classification*. Class II (performance standards).

## § 868.5860 Pressure tubing and accessories.

(a) *Identification*. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

## § 868.5870 Nonrebreathing valve.

(a) *Identification*. A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

(b) *Classification*. Class II (performance standards).

## § 868.5880 Anesthetic vaporizer.

(a) *Identification*. An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

(b) *Classification*. Class II (performance standards).

## § 868.5895 Continuous ventilator.

(a) *Identification*. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification*. Class II (performance standards).

## § 868.5905 Noncontinuous ventilator (IPPB).

(a) *Identification*. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.

(b) *Classification*. Class II (performance standards).

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## § 868.5915 Manual emergency ventilator.

(a) *Identification*. A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

## § 868.5925 Powered emergency ventilator.

(a) *Identification*. A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

## § 868.5935 External negative pressure ventilator.

(a) *Identification*. An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.

(b) *Classification*. Class II (performance standards).

## § 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification*. An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

(b) *Classification*. Class II (performance standards).

## § 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification*. A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

(b) *Classification*. Class II (performance standards).